

June 4, 2015

Honorable Charles E. Grassley
Chairman
Committee on the Judiciary

Honorable Patrick J. Leahy
Ranking Member
Committee on the Judiciary

Honorable John Cornyn
Honorable Orrin G. Hatch
Honorable Michael S. Lee

Honorable Charles E. Schumer
Honorable Amy Klobuchar

Dear Chairman Grassley, Ranking Member Leahy, and Senators Cornyn, Schumer, Hatch, Klobuchar and Lee:

On behalf of BIO and our members, I'd like to thank you for your good faith efforts to put together a package of reforms to the PTO's *inter partes* review (IPR) and post-grant review (PGR) proceedings, aimed at addressing our concerns about the basic fairness of these proceedings to patent owners. While essential additional reforms are necessary to ensure that the overall PATENT Act reflects an appropriate balance between the interests of those who seek to enforce patent rights and those who are accused of infringement, we sincerely appreciate your efforts to date and your commitment to continue working with us to achieve a final bill that BIO can support before it is taken up by the full Senate.

With respect to the legislation that was considered by the Senate Judiciary Committee earlier today, we want to thank you for including several provisions, including the elimination of the PTO's misguided claim construction standard, that will help address concerns of unwarranted PTO invalidations of patents and inconsistent validity determinations between PTO and court proceedings. We also appreciate your inclusion of provisions that will give patent owners greater substantive and procedural rights in these PTO proceedings, as well as the important statutory clarification that the PTO Director has discretion to deny any IPR or PGR petition that is contrary to the interests of justice.

As you know, the growing evidence that IPR is a proceeding that is heavily skewed in favor of patent challengers and in which it is far easier to kill patents than in court is encouraging various forms of abusive practices aimed at gaming the differential standards between the two systems. It also is undermining the confidence of biotechnology investors and businesses who must be able to rely on the government's issuance of patent rights to justify the massive investment, over a decade or more, in developing the next generation of innovations to help heal, fuel, and feed the world.

The IPR/PGR reforms that were added by the Managers Amendment include important steps forward in addressing these concerns. That said, we continue to believe strongly that the most effective way to prevent gamesmanship and abuse of the IPR system is by reducing concurrent, duplicative, and serial proceedings in the PTO and courts, and by ensuring that the evidentiary standards used in IPR proceedings are the same as those used in the courts so that there is no systematic legal advantage of proceeding in one forum over the other. Because the provisions included in the reported bill do not resolve such concerns, we have encouraged you to consider other meaningful approaches that could be taken to minimize the incentives that are leading to such abusive practices, particularly with respect to patents covering approved drug and biological products that are subject to unique and

highly detailed statutory regimes governing patent dispute resolution and litigation. It is essential that the PATENT Act seek to preserve the integrity of these carefully balanced, Congressionally-created processes. We remain dedicated to working out a path forward before the bill reaches the Senate floor, and we appreciate the commitments you have made in this regard.

We also want to continue working with you on the critical efforts to ensure patent owners have a meaningful ability to amend claims in IPR/PGR. We understand the current language in the reported bill on this issue is a placeholder, as BIO and other stakeholders continue efforts to craft mutually acceptable language. Further, we strongly urge modification of the effective date provision to ensure that all of the key IPR/PGR reforms in your bill go into effect at the earliest possible time. The hundreds of patent owners facing currently pending PTO proceedings should not have to continue to suffer from the unfair decisions made by the PTO in implementing these new proceedings – and Congress must avoid incentivizing the filing of thousands of more IPRs by those seeking to benefit from the current and biased rules before the bill's important changes go into effect.

In recognition of the good faith of you and your staffs in crafting the important reforms included in your Manager's Amendment, and your commitments to continue to work with BIO to address our remaining concerns prior to Senate floor consideration, BIO did not oppose your efforts to move the legislation forward through the Senate Judiciary Committee. BIO reserves the right to seek further changes as described above, and we will determine our position on the final legislation at the appropriate time.

Thank you again for all your hard work in improving both the litigation-related and IPR/PGR reforms contained in in the reported bill. We look forward to continuing to work with you to include further improvements as the legislative process moves forward, and BIO remains optimistic that we can achieve a final bill that BIO can fully support rather than oppose.

Sincerely,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is written in a cursive style with a large, looping initial "J".

James C. Greenwood
President & CEO